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ONE HUNDRED NINTH CONGRESS

# Congress of the United States

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2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074  
FACSIMILE (202) 225-3974  
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### Statement of Rep. Henry A. Waxman on S. 172 October 26, 2005

I rise to join my colleagues, particularly John Boozman, in supporting this important bill to apply the highest safety standard and consumer protections to all contact lenses.

This legislation became necessary on April 4, 2003. On this day, the Food and Drug Administration decided to classify certain colored contact lenses as cosmetics, not medical devices. This classification made no sense. Cosmetics are not required to be made according to strict manufacturing standards. Cosmetics are not reviewed for safety prior to marketing. And cosmetics are not prescribed by a doctor. The loose regulatory approach to cosmetics may work for lipstick, but it is dangerous for contact lenses, which are placed directly in they eyes. If contact lenses are not made properly they can cause severe infections. If lenses do not fit properly, they can cause disfiguring ulcers. And if lenses are worn by teenagers or others without the ongoing supervision of an eye-care professional, severe injuries can result.

Since April 4, 2003, scores of teenagers and young adults have been injured by cosmetic contact lenses. Some have permanently lost vision. Others have required corneal transplants. In one survey in Louisiana, 85% of optometrists and 45% of ophthalmologists reported diagnosing eye injuries from contact lenses sold without a prescription.

Since April 4, 2003, I have worked with Congressman Boozman, contact lens manufacturers, the American Academy of Ophthalmology, the American Optometric Association, and consumer advocates, to ensure that all contact lenses are regulated according to the strict standards and consumer protections under the safeguards applied to medical contact lenses.

In the 108<sup>th</sup> congress, our resolution passed House but not the Senate. In late July of this year, the legislative approach that we designed passed the Senate. It is this legislation that has come before the House. By passing this bill, we can ensure that FDA protects consumers from unsafe contact lenses. We can prevent serious eye injuries, even blindness, and we can send a timely message to teenagers and their parents about the dangers of unsupervised use of contact lenses at Halloween.

I would like to express my appreciation to Senators DeWine and Kennedy regarding this legislation for guiding this legislation through the Senate. I would like to thank those at FDA who supported our legislative solution, and I recognize the efforts of experts such as Thomas Steinaman in Cleveland, who worked hard to raise awareness about the availability and dangers of unsafe lenses. And I especially want to thank and congratulate our colleague Congressman Boozman for his persistence and hard work in the House of Representatives. I urge my colleagues to support this bipartisan consensus legislation today.